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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,384	10/13/2000	T.G. Dinan	99,829-A	7338

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EXAMINER
JAGOE, DONNA A

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/31/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/687,384	Applicant(s) DINAN ET AL.	
	Examiner Donna A. Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-6 are presented for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites "a method according to claim 1 in which the gastrointestinal diseases are characterized as non-ulcerative dyspepsia or irritable bowel syndrome or chemotherapy-associated disorders of motility **including** nausea". The word "including" renders the claim indefinite because it is unclear whether the limitations following the word "including" are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Dinan et al. U.S. Patent No. 5,403,848 A.

The claim is drawn to a method for preventing and treating gastrointestinal disease by means of administration of an effective amount of an antagonist or partial agonist of 5HT1a receptors.

Dinan et al. teach a method of treating a gastrointestinal disorder using a 5HT1a receptor agonist/antagonist such as buspirone and cyproheptadine (see abstract and example 3, column 7, line 45 to column 8, line 17).

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Gaster et al. U.S. Patent No. 6,159,979 A.

Gaster et al. teach methods of use for 5HT1a receptor antagonists for treatment of disorders of the gastrointestinal tract where changes in motility and secretion are involved (column 6, lines 57-65).

3. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Brandes U.S. Patent No. 5,859,065 A.

The claim is drawn to a method for preventing and treating gastrointestinal disease by means of administration of an effective amount of an antagonist or partial agonist of 5HT1a receptors and methods of use in chemotherapy-associated disorders of motility.

Brandes teaches administration of a 5HT1(a) antagonist such as cyproheptadine (column 6, lines 1-2) for gastrointestinal side effects associated with chemotherapy, namely nausea, vomiting, anorexia and stomatitis (column 2, lines 32-40).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Dinan et al. U.S. Patent No. 5,403,848 A, Gaster et al. U.S. Patent No. 6,159,979 A, and Brandes U.S. Patent No. 5,859,065 A each taken individually.

1. Dinan et al. teach that 5HT1a receptor agonist/antagonist such as buspirone and cyproheptadine may be employed for treating a gastrointestinal disorder (see abstract).

Dinan et al. does not teach administration of racemic pindolol.

Since it is known that 5HT1a receptor antagonists or partial agonists are useful for treating gastrointestinal disorders, it would have been obvious to substitute pindolol,

a 5HT1a antagonist. It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532.

2. Gaster et al. teach methods of use for 5HT1a receptor antagonists for treatment of disorders of the gastrointestinal tract where changes in motility and secretion are involved (column 6, lines 57-65).

Gaster et al. does not teach administration of racemic pindolol.

Since it is known that 5HT1a receptor antagonists or partial agonists are useful for treating gastrointestinal disorders, it would have been obvious to substitute pindolol, a 5HT1a antagonist. It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532.

3. Brandes teaches administration of a 5HT1(a) antagonist such as cyproheptadine (column 6, lines 1-2) for gastrointestinal side effects associated with chemotherapy, namely nausea, vomiting, anorexia and stomatitis (column 2, lines 32-40).

Brandes does not teach administration of racemic pindolol.

Since it is known that 5HT1a receptor antagonists or partial agonists are useful for treating gastrointestinal disorders, it would have been obvious to substitute pindolol, a 5HT1a antagonist. It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna A. Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on 6:30 A.M. - 3 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 308-7921 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0193.

DWAYNE C. JONES
PRIMARY EXAMINER, 1614

dj
December 27, 2001